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EXAMINER

AFREMOVA, VERA

ART UNIT

PAPER NUMBER

1651

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4

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
10/060,551

Applicant(s)  
Hwang

Examiner  
Vera Afrem va

Art Unit  
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 27, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above, claim(s) 6 and 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Applicant's election without traverse of the Group I invention (claim 1-5) in Paper No. 3 is acknowledged. Claims 6 and 7 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Claims 1-5 are under examination in the instant office action.

#### ***Claim Objections***

Claims 1-3 are objected to because of the following informalities:

Claim 1 should contain the full Latin name of microorganism. The abbreviated name might be used thereafter. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 4 and 5 are indefinite because it is not clear whether the "components selected from the peaks" are unique materials or unique compounds. The claims as written are not informative with respect to the material intended and the examination based in the spectra as claimed is practically impossible. Furthermore, the results obtained for the peaks or spectra in the figures would be reasonably expected by one of ordinary skill in the art to depend on conditions including solvents, degree of purification of extracts or components, rate of solvent flow, etc. Thus, these claims fail to point out the subject matter which applicant regards as the invention.

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In the instant office action claims 1, 3, 4 and 5 are given broad interpretation as drawn to the use of an aqueous plant extract.

Claims 1 and 4 are indefinite with respect to the distinction between “therapeutically effective amount” and “effective amount”. The disorder such as *Otitis media* is caused by the infection or adhesion of cells of *H.influenza* (see specification page 7, par. 1). Moreover, the issue of dosage or “effective” amount is uncertain in the light of applicant’s definitions. For example: effective dosage for compositions characterized by “peaks 1, 6 and 7” is 0.01 gms per day (see claim 2 or see specification page 8, lines 14-16). However, the minimum “effective” amount for the same composition in the specification appears to be 40 times higher, for example: 0.4 gms per day (specification page 14, lines 6-7). Thus, the required “effective” amounts for inhibiting attachment of *H.influenza*, for treatment of *Otitis media* and/or for prevention of *Otitis media* are uncertain as claimed and in the light of applicant’s definitions. With respect to claim 4 it is also unclear whether the same amount required for the “treatment” and for “prevention” of *Otitis media*.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,776,462.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the similar methods of inhibiting attachment of *H.influenza* and/or treating/preventing *Otitis media* by administering a composition comprising effective amount of an aqueous extract of *Pogostemon cablin*. The scope of the extract in the claims of the instant application and of the extract of the patented claims is identical regardless the fact that claims refer to different figures. The figures 1, 2 and 4 demonstrate profiles of the same extract "P10E" which is an aqueous extract of *Pogostemon cablin*.

The claims of the patent 5,776,462 are limited to a particular mode of administration such as "orally or nasally". Claims of the instant application are broader and they are not limited to a particular mode of administration such as "orally or nasally" as the claims of U.S. Patent

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No. 5,776,462. However, it is reasonable to expect that patients with *Otitis media* which is caused by nasal, nasopharyngeal or buccal adhesion or infection with *H.influenza* would be treated orally and/or nasally in order to inhibit nasal, nasopharyngeal or buccal infection with *H.influenza*.

Accordingly, the claimed methods are obvious variants. Thus, the inventions as claimed are co-extensive.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by CN 1078399 [O].

Claims are directed to a method of inhibiting attachment of *H.influenza* and/or treating/preventing *Otitis media* by administering to a human patient a composition comprising effective amount of an aqueous extract of *Agastache rugosa*.

The cited patent CN 1078399 teaches a method of administering to a human patient a composition comprising effective amount of an aqueous extract of *Agastache rugosa* (see English abstract and official translation page 7, par. 2).

The cited patent CN 1078399 is considered to anticipate the claimed invention since both methods are one active step methods comprising one active step of administering an identical

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composition comprising effective amount of an aqueous extract of *Agastache rugosa*. Thus, administration of identical composition is reasonably expected to provide identical effects with regard to the use of components derived from aqueous extract of *Agastache rugosa* including effects such as inhibiting attachment of *H.influenza* and/or treating/preventing *Otitis media*. Moreover the cited patent teach that administration of a composition with aqueous extract of *Agastache rugosa* resulted in alleviation of dizziness and nasal obstruction (page 7, par. 2, line 10) which are symptoms of *Otitis media*.

Although the composition comprising an aqueous extract of *Agastache rugosa* of the cited patent is not disclosed as being characterized by “peaks 1, 6 and 7 of C18- HPLC” as intended for the applicant’s extract of claims 1 and 4, the composition in the cited method is reasonably expected to comprise the same “at least one” active ingredient or component as the claimed aqueous extract of *Agastache rugosa*, because the cited patent teaches that administration of a composition with the aqueous extract of *Agastache rugosa* resulted in alleviation of dizziness and nasal obstruction (see page 7, par. 2, line 10) which are symptoms of *Otitis media*.

Claims 1, 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 08176002 [P].

Claims are directed to a method of inhibiting attachment of *H.influenza* and/or treating/preventing *Otitis media* by administering to a human patient a composition comprising effective amount of an aqueous extract of *Agastache rugosa*. Some claims are further drawn to

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administration of the amount of at least 0.01 gms per day and more in the method of inhibiting attachment of *H.influenza* and/or treating/preventing *Otitis media*.

JP 08176002 teaches a method of treating and/or preventing cell adhesion by administering to a patient a composition comprising effective amount of an aqueous extract of *Agastache rugosa* (English abstract; see official translation at page 3, par. 0007, at page 4, par. 0009, line 2, at page 4, par. 0010, line 2, at page 5, par. 0017). The cited patent teaches an effective amount of at least 20 mg par day per kg of patient body (translation page 4, last par.). The patient under treatment is a general patient in need of the treatment including a human patient. of inhibiting attachment of *H.influenza* and/or treating/preventing *Otitis media*.

The cited patent JP 08176002 is considered to anticipate the claimed invention since both methods are one active step methods comprising one active step of administering an identical composition comprising effective amount of an aqueous extract of *Agastache rugosa*. Thus, administration of identical composition is reasonably expected to provide identical effects with regard to the use of components derived from aqueous extract of *Agastache rugosa* including effects such as inhibiting attachment of *H.influenza* and/or treating/preventing *Otitis media*. Moreover, the cited patent teach that administration of a composition with aqueous extract of *Agastache rugosa* inhibits cell adhesion or attachment and it provides effects related to alleviation of distress of upper respiratory tract including nasopharyngeal obstruction (see page 7, par. 0017). According to the applicant' definitions a treatment or prevention of *Otitis media* associated with treatment cold symptoms (page 34, line 1) and sore throat (page 31, line 10) which are distress of upper respiratory tract including nasopharyngeal obstruction.

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With respect to the claim 2 the cited patent is considered to anticipate the claimed invention because the dose range or the dosage protocol are overlapping. The claimed method requires administration of at least 0.01 gms per day and more. The cited patent teaches at least 20 mg par day per kg of patient body.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over CN

1078399 [O] and JP 08176002 [P] taken with CN 1078399 [N].

Claims are directed to a method of inhibiting attachment of *H.influenza* and/or treating/preventing *Otitis media* by administering to a human patient a composition comprising effective amount of an aqueous extract of *Agastache rugosa*. Some claims are further drawn to administration of the amount of at least 0.01 gms per day and more in the method of inhibiting attachment of *H.influenza* and/or treating/preventing *Otitis media*.

The cited patents CN 1078399 [O] and JP 08176002 [P] are relied upon as explained above for the disclosure of methods of administering to human patients compositions comprising effective amounts of an aqueous extract of *Agastache rugosa*. The disclosed effects include inhibiting of cell adhesion and alleviation of symptoms of *Otitis media* including distress of

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upper respiratory tracts. Although the cited CN 1078399 [O] is silent with regard to a dose or a minimum dosage in the method for administration, the cited JP 08176002 [P] discloses a dosage protocol which is coextensive with the presently claimed dosage protocol. The cited patents are silent with regard to treatment or prevention of all symptoms associated with *Otitis media*, for example: sore throat.

However, the cited patent CN 1078399 [N] discloses effects of herbal tea compositions comprising aqueous extract of *Agastache rugosa* including moisturizing dry or sore throat (translation page 1, last paragraph; page 2, par. 6, line 4).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to practice the methods of CN 1078399 or CN 1063796 with a reasonable expectation of success in treating disorders related cell attachment including attachment of *H.influenza* and/or in treating/preventing distresses associated with *Otitis media* including nasal obstruction and sore throat since it is known that compositions comprising aqueous extract of plant *Agastache rugosa* are inhibitors of cell adhesion and that this extract have been taught/suggested for alleviation of symptoms similar to that of *Otitis media* including distress of nasopharyngeal area and/or sore throat. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

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The scope of the claims 3 and 5 is free from prior art because the Figures 1A, 1B, 3A and 3B demonstrate characterization of the aqueous extract of *Pogostemon cablin* but not the aqueous extract of *Agastache rugosa*. For example: the extracts which are disclosed as P10E-1 and P10E2 on the Figures 1A, 1B, 3A and 3B (see specification pages 10-11) are obtained from *Pogostemon cablin* (see specification page 14, line 12 and page 16, line 6) but not from *Agastache rugosa*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova

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April 17, 2003.

VERA AFREMOVA

PATENT EXAMINER

